



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Arcadi Marcovich, President
Haifa Smoked Fish, Inc.
94-15 150th Street
Jamaica, NY 11435

July 25, 2001

Ref: NYK-2001-103

Dear Mr. Marcovich:

We inspected your fish processing firm, located at the above address, on June 6 through 28, 2001. During the inspection, we also collected samples of your finished products. Our laboratory analysis of your vacuum packed cold-smoked sea bass (lot no. 0604) and vacuum packed cold-smoked salmon (lot no. 0606) found them to contain less than the minimum 3.5 percent water phase salt required by your vacuum packed smoked fish HACCP plan and process schedules.

The Seafood HACCP regulations (Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)) require that your HACCP plan monitoring procedures and frequencies at each of the critical control points be adequate to ensure compliance with critical limits (e.g., minimum water phase salt) (21 CFR 123.6(c)(4)). The regulations also require that every processor verify that the HACCP plan is adequate to control food safety hazards and that the plan is being effectively implemented (21 CFR 123.8(a)). These serious deviations from the HACCP requirements cause your vacuum packaged ready-to-eat smoked fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we

Haifa Smoked Fish, Inc.

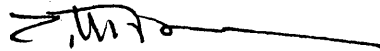
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expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Form FDA 483) issued to and discussed with you at the conclusion of the inspection may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. W. Thomas', followed by a long horizontal line extending to the right.

Edward W. Thomas
Acting District Director